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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,784	11/19/2004	Ayaaki Ishizaki	2004-1526A	8456

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SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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12/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/508,784

Applicant(s)

ISHIZAKI ET AL.

Examiner

Deborah K. Ware

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,7,8,10,11,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,7,8,10,11,13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 5, 7-8, 10-11 and 13-14 are presented for examination on the merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 24, 2007, has been entered.

Response to Amendment

The amendment, remarks and extension of tem filed September 24, 2007, have been received and entered of record. Further, the miscellaneous transmittal form filed September 24, 2007, has been received.

Claim Objections

Claims 8 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form. These claims depend from canceled base claims and, therefore, they can not not further limit these claims. Alternatively the claims are objected to for simply being dependent upon canceled base claims.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claim 7 be found allowable, claim 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 7-8, 10-11 and 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 7-8, 10-11 and 13 are rendered vague and indefinite for the recitation of "(3)" and "(4)" and "(5)" in claim 5 at lines 10 and 17 and claim 13, at line 3, respectively, because it is unclear whether these values are intended to be part of the calculation in terms of numerical multipliers or whether they are simply referring to equation (3) and equation (4) as recited in each of lines 9 and 16 of claim 5 and equation (5) at line 3 of claim 13, respectively. Deletion of "(3)" and "(4)" at lines 10 and 17 and "(5)" of claim 5, and at line 3 of claim 13 is suggested.

Claims 5, 7-8, 10-11 and 13-14 recite the terms "substrate" and "the substrate" in lines 20, 21, 24 and 25 of claim 5 and in lines 10, 11, 14, and 17 of claim 14. There is insufficient antecedent basis for this limitation in the claim. It is further unclear when the bleeding step is performed on the culture liquid whether or not the culture liquid is from the glucose substrate or not since it is the substrate that is returned to the fermenter and the cells are removed from it as well. The metes and bound of the claim can not be determined. Also the process steps have not been clearly set forth to distinctly and clearly describe the claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 7-8, 10-11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Siano (US 6284453) and if necessary in view of newly cited EP 0120370 (EP), both cited on enclosed PTO-892 Form.

Claims are drawn to methods for continuous anaerobic culture in a fermenter wherein glucose and alkaline feeds are alternately provided to control pH and glucose concentration of the fermentation process by performing and carrying out calculations to determine when to add glucose substrate or alkaline solution based upon pH.

Siano teaches methods for continuous anaerobic culture in a fermenter wherein glucose and alkaline feeds are alternately provided to control pH and glucose concentration of the fermentation process by performing and carrying out calculations to determine when to add glucose substrate or alkaline solution based upon pH (note col. 2, line 30-35; col. 3, lines 40-65; col. 4, lines 4-5 and lines 55-60; col. 6, line 1; col. 10, lines 15-60; col. 13-15, all lines and col. 19, lines 44-45). Specifically, at col. 15, lines 30-40, it is noted that overfeeding of glucose substrate will decrease pH because of lactic acid production and underfeeding of it will cause slow growth. Siano controls glucose concentration by feeding glucose substrate at a rate based on an alkaline

consumption per unit time via calculations based upon pH and even a lower limit of pH. Also ethanol and lactic acid production are disclosed, see above noted citations.

EP teaches methods for continuous anaerobic culture in a fermenter wherein glucose and buffer salts are used to control pH. Note the abstract. Furthermore, at a higher pH glucose substrate is added, note page 11, lines 9-15. EP clearly discloses using pH as an indicator to add glucose substrate. Buffering inorganic salts were also disclosed to be added to the fermentation medium. EP teaches an upper and lower limit of pH for which to practice their method, page 8, line 6.

The claims differ from Siano in that the specific calculations as claimed are not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to perform calculations based upon feeding glucose substrate and alkaline solution alternately to control pH at a predetermined level as disclosed by the cited prior art.

Siano clearly teaches that these calculations are fast, accurate, robust and autoclavable, note col. 4, lines 55-59. While EP does not specifically teach calculations, it does disclose using measurements to obtain fast and accurate results. Siano clearly suggests that to add substrate when pH is high or at the upper limit because the lactic acid in the culture medium would be lower giving a higher pH value. Thus, growth rate would be slower at a higher pH and to add more glucose substrate to stimulate growth rate would have been expected to provide successful results.

Likewise when pH is low, to add alkaline NaOH solution as disclosed by Siano would have been expected to provide successful results because optimal results are measured and obtained by Siano through biofeedback to maintain optimal culture conditions. Siano clearly suggest, if not teach continuous culture, wherein recycling of substrate and removal of cells would have been routine by an ordinary artisan. To select for NaOH as a coefficient of normality of the fermentation is clearly an obvious modification of the cited prior art.

Further, to use a term for adjustment of glucose concentration is also an obvious modification of the art. Clearly each of the parameters as claimed for carrying out the measurements are either disclosed or suggested by the cited prior art. Each of ethanol and lactic acid are also disclosed. Also dilution of the culture fluid is clearly an anticipated feature of the teachings of Siano as alkaline solution agent is clearly taught and used to control pH of the culture fluid. The claims are rendered prima facie obvious over the cited prior art.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


DEBORAH K. WARE
PATENT EXAMINER
Deborah K. Ware
December 9, 2007